Nelson, Bettie L
From: Roethig, Hans
Sent: Wednesday, August 14, 2002 12:59 PM
To: 'Doug.Fulling@mdsps.com'; Roethig, Hans; Anthony.Cavaliere@mdsps.com
Cc: Theresa.Ockershausen@mdsps.com; Nelson, Bettie L; Liang, Qiwei
Subject: RE: MDS questions for TES proposal

Dear Dough,
the assumptions are correct. At this moment it is my assumption that there will be no coding necessary, we also do not need a SAE database like in drug trials.

Best regards
Hans

-----Original Message-----

From: Doug.Fulling@mdsps.com [mailto:Doug.Fulling@mdsps.com]
Sent: Wednesday, August 14, 2002 10:58 AM
To: Hans-Juergen.Roethig@pmusa.com; Anthony.Cavaliere@mdsps.com
Cc: Theresa.Ockershausen@mdsps.com
Subject: RE: MDS questions for TES proposal

Hi Hans,

It was a pleasure meeting the team and we look forward to learning more about your initiatives for 2003. I am in the King of Prussia office today and working with Tony on our revised proposal. As we are working on the proposal, we wanted to clarify a couple of points:

- We are assuming the eCRF system utilized will be cleaning and capturing the data
- We are assuming that we will be receiving lab data electronically
- We are assuming that we will be receiving the questionnaire file with scanned data

Please let me know if these assumptions are correct and will be able to turn around a budget estimate to you quickly. Also, let me know if there are any line items you would like us to remove from our previous proposal, ex: coding.

With our assumptions and the information you shared with us, we feel we can significantly reduce our original budget estimate.

On another note, per your question about Central Labs and data validation, please find the MDS Pharma Services' perspective below. *If you have further questions, I would be happy to put you* in touch with a representative from Central Labs.

Best regards,
Doug

Please find the following explanation of our data cleaning process for Central Lab. This process along with the trial size, complexity, number of testing locations, data interchange volume, study testing profile and required resources to guarantee data quality are included as part of our charge for electronic data transfers. Please note that we only invoice clients for actual data transfers.

"Data cleaning at MDS Pharma Services Central Lab is a two-stage process.

First stage is carried out during data acquisition and covers the following:

General management of the study.
The bioanalytical needs not to be costed.
Please keep all this information strictly confidential according to the Philip Morris-MDSPS master contract.

Please call me if you have any questions.
Best regards

Hans J Roethig, MD, PhD, FCP, FFPM
Director Clinical Evaluation
Philip Morris USA
615 Maury Street
Richmond, VA 23224
Phone: (804) 274-3165
Fax: (804) 274-2891
Mobile phone: (804) 687-1655
e-mail: hans-juergen.roethig@PMUSA.com

<<SAMPLING STRATEGY_7.doc>>
<<analysis plan draft for tes 5_16_02_bln.doc>>
<<Protocol 8451-Final Draft Version 1.1- 03 July 2>>